

# Notice of Allowability

Application No.

09/869,004

Examiner

Joyce Tung

Applicant(s)

BRESLAUER ET AL.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/15/2004.
2. ☒ The allowed claim(s) is/are claims 50-56 (final claims 1-7).
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All b) ☐ Some\* c) ☐ None of the:
    1. ☒ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 6/22/01
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 6/2/2004.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

### EXAMINER'S AMENDMENT

The applicant's response filed 4/15/2004 to the Office action has been entered. Claims 50-56 are pending.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

1. Authorization for this examiner's amendment was given in a telephone interview with Ms. Kathleen A. Tyrrell on June 2, 2004.

The application has been amended as follows:

In claim 51, step (c), line 4, delete "the".

2. The following is an examiner's statement of reasons for allowance:

Concerning claims 50-56, no prior art has been found teaching or suggest a method for screening for nucleic acid duplex stability by competitive equilibria, comprising: (a) producing a solution containing a known amount of an initial nucleic acid duplex with a known stability, the initial nucleic acid duplex comprising a first nucleic acid strand having a sequence wholly or in part homologous to a target strand and labeled with a donor of a FET pair and a second nucleic acid strands having a sequence wholly or in part complementary to the target strand and labeled with an acceptor of the FET pair; (b) titrating the solution with a second solution comprising a known concentration of the target nucleic acid strand which competes with the first nucleic acid strand of the initial nucleic aid duplex of step (a) for binding to the second nucleic acid strand of the initial nucleic acid duplex of step (a); (c) subjecting the titrated solution to conditions which

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disrupt the initial nucleic acid duplex of step (a) and any duplex or triplex formed between the target strand and the second nucleic acid of the initial nucleic acid duplex of step (a) upon titration in step (b), but which do not disrupt the target strand when double stranded; (d) subjecting the titrated solution to conditions which promote duplex or triplex formation and (e) monitoring the titration solution for changes in the amount of initial nucleic acid duplex formed as a function of the amount of target nucleic acid strand added by measuring changes in FET donor or acceptor intensity. The method is also applied for detecting a single nucleotide polymorphism, and determining the concentration of a target nucleic acid sequence.

The closest prior art is the reference of Breslauer et al. Breslauer et al. disclose the complete thermodynamic characterization of all 10 nearest-neighbor interactions in a Watson-Crick DNA duplex structure. These data can be used in predicting the stability of gene-probe complex selection optimal conditions for hybridization, deciding on the minimum length of a probe, predicting the influence of specific transversion or transition on the stability of an affected DNA region (See pg. 3746, the Abstract). Breslauer et al. do not disclose the method of screening for nucleic acid stability by competitive equilibria comprising the steps as set forth in claims 50-56 and applying the method for detecting a single nucleotide polymorphism, and determining the concentration of a target nucleic acid sequence.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung  
June 2, 2004

  
GARY BENZION, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
6/10/04

For Ken Herklich